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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,745	06/27/2003	Peter Gluckman	704652-9001	5345

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San Francisco, CA 94111-4067

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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07/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,745

Applicant(s)

GLUCKMAN ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,28 and 64-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,28 and 64-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/185,804.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070628</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on February 28, 2007 and June 28, 2007 have been entered.

2. The amendment to the specification filed June 28, 2007 does not accurately mark all changes made to the paragraph at column 1, lines 3-8, of U.S. Patent No. 5,714,460, as is required by 37 CFR 1.173(b)(1). In particular, at line 4 of the amended paragraph, the comma which originally appeared after "abandoned" has been omitted without the change being marked with brackets. At line 11 of the amended paragraph, "USC" has been changed to "U.S.C." without the change being appropriately marked. Correction is required, by submission of a new version of the amended paragraph, with all changes relative to the version of paragraph occurring in the '460 patent being accurately marked.

3. The maintenance fees due at 3.5 years and 7.5 years after the issue date of U.S. Patent No. 5,714,460 have been paid, and therefore the reissue procedures are available for this patent.

This reissue application was filed within two months of the mailing date of the final judgment of interference 104,553, and therefore the reissue procedures are available for this patent.

4. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required*

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by 37 CFR 1.172(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b).

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

Papers attempting to establish the consent of assignee to the reissue were filed on November 1, 2004. However, the papers are contradictory. One paper, signed by Timothy R. Schwartz, PhD., states that Genentech, Inc. is the owner of the entire right, title and interest in and to U.S. Patent No. 5,714,460. A second paper, signed by Paulina Lucrynska (sp.?), states that NeuronZ Limited is the owner of the entire right, title and interest in and to U.S. Patent No. 5,714,460. Two separate legal entities cannot each be the owner of the entire right, title and interest in a single U.S. patent. Further, according to the assignment records of the U.S. Patent and Trademark Office, NeuronZ LTD is the only assignee of record for U.S. Patent No. 5,714,460. Correction is required.

5. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,583,114 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 16, 28, and 64-77 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

See MPEP § 1414.01.

As set forth in MPEP 1444(II), it is suggested that Applicants wait until this application is otherwise in condition for allowance, and all substantive amendments to the application have been made, before submitting the supplemental reissue declaration.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 16, 28, 66, 67, 72, and 73 are rejected under 35 U.S.C. 103 as being estopped on the merits by final judgment in Interference No. 104,533. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. The interference count does not recite that the CNS injury predominately affects glia. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to

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treat glial cells damaged by CNS injury which predominantly affects glia, because the interference count specifically recites that injured glia cells are to be treated, and the lack of injury to other types of cells would not have been expected to interfere with the ability of IGF-1 and its analogues to treat injured glia cells. With respect to claims 66, 67, 72, and 73, these claims recite the same or broader limitations as are recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Accordingly, claims 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over the lost count.

9. Claims 16, 28, 66, 67, 72, and 73 are rejected under 35 U.S.C. 102(g) and/or 103 as being estopped on the merits by final judgment in Interference No. 104,533. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. With respect to claims 16, 28, 66, 67, 72, and 73, these claims recite the same or broader limitations as is recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count.

Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Further, Applicants' specification at column 1, lines 44-46, acknowledges that multiple sclerosis is a disease of the CNS which causes the loss of oligodendrocytes (which are a type of glia cells). This section of Applicants' specification is quoted in section [19] of the Decision On Motions. See also section [93] of the Decision On Motions. Accordingly, the count, which suggests treating glial cells which are injured by multiple sclerosis, also suggests the broader limitation of treating glial cells damaged by CNS injury which predominantly affects glia. Claims 16, 28, 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over (or even anticipated by) the lost count.

10. Applicant's arguments filed June 28, 2007 have been fully considered but they are not persuasive.

The objection under 37 CFR 1.172(a) based upon non-establishment of ownership interest in the patent for which reissue is being requested, set forth in section 4 above, is

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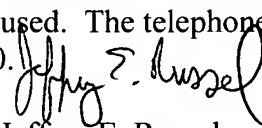
maintained. The new forms discussed by Applicants at page 8 of the response have not yet been received.

Certain of Applicants' claims remain rejected on the basis of interference estoppel. See sections 8 and 9 above. Applicants' arguments with respect to this issue (see pages 12-14 of the response) duplicate those arguments submitted in the proposed amendment after final filed February 28, 2007. The examiner maintains his position on this issue for the reasons of record. See, e.g., the Office action mailed August 29, 2006, page 10, second paragraph, and the Office action mailed April 4, 2007, section 8.

The declaration under 37 CFR 1.132 by Bonni filed June 28, 2007 is a duplicate of the declaration filed February 28, 2007, and has the same effect with respect to the rejection under 35 U.S.C. 112, second paragraph, as the earlier-filed declaration.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.


Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
July 10, 2007